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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/990,310  | 11/23/2001  | Kunio Doi            | 215808US20          | 2678             |
| 22850   | 7590        | 04/19/2004           | EXAMINER            |                  |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      | DASTOURI, MEHRDAD   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 2623                |                  |

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/990,310

Applicant(s)

DOI ET AL.

Examiner

Mehrdad Dastouri

Art Unit

2623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>g</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicants' amendment filed January 28, 2004, has been entered and made of record.

2. The Declaration under filed on January 28, 2004 under 37 C.F.R. § 1.131 has been considered but is ineffective to overcome the U.S. Patent Publication 2002/0172403 reference. Inventor Kunio Doi has not signed the declaration.

3. Objection to Claim 12 has been withdrawn in view of Applicants' amendment.

Applicant's arguments filed January 28, 2004, regarding alternate rejection of Claims 1-14 have been fully considered but they are not persuasive.

Applicants argue that prior arts of record (Doi '374 and Ema) do not disclose patient' age or gender as a factor in evaluating whether a pulmonary nodule is malignant.

The examiner disagrees and indicates that sex (gender) and age (date of birth) of the patient are among the factors considered by Ema (Tables 5, 6, 7 and 10).

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Doi et al., US 2002/0172403 (hereinafter Doi).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As per claim 1, Doi teaches:

obtaining at least one computed tomography medical image of the pulmonary nodule [0027];

obtaining at least one patient feature (age, [0078] or sex, [0089]) of a patient;  
extracting image features [0067] of the pulmonary nodule from the at least one computed tomography medical image;

evaluating whether the pulmonary nodule is malignant based on an examination of a total of seven [0086]-[0097] of the patient or image features.

As per claim 2, Doi teaches:

wherein the step of obtaining at least one computed tomography medical image comprises obtaining a medical X-ray image [0110].

As per claim 3, Doi teaches:

wherein the step of obtaining at least one computed tomography medical image comprises obtaining at least one low-dose computed tomography image [0085].

As per claim 4, Doi teaches:

wherein the step of obtaining at least one patient feature comprises obtaining at least one of sex [0089] and age[0078] of the patient having the pulmonary nodule [0085].

As per claim 5, Doi teaches:

identifying image features based on an outline of the at least one computed tomography medical image of the pulmonary nodule [0037];

identifying image feature based on linear patterns of the at least one computed tomography medical image of the pulmonary nodule [0037], [0073], 0075], [0093];

identifying image feature based on edge orientation of an edge gradient ([0068] edge magnitude and direction); of the at least one computed tomography medical image of the pulmonary nodule

identifying image feature based on gray-level distribution [0035] of the at least one computed tomography medical image of the pulmonary nodule;

identifying image feature based on gray-level distribution of an edge gradient [0069] of the at least one computed tomography medical image of the pulmonary nodule;

identifying image feature based on the relationship between two histograms in the inside and outside regions of the segmented nodule [0064] of the at least one computed tomography medical image of the pulmonary nodule;

identifying image feature based on the relationship between two histograms in the inside and outside regions of the segmented nodule of an edge gradient [0064] of the at least one computed tomography medical image of the pulmonary nodule.

As per claim 6, Doi teaches at least one of the following steps:

identifying the effective diameter of the outline [0067]

As per claim 7, Doi teaches:

identifying the magnitude of line patterns for inside region of a segmented nodule of the medical image [0068]; and

identifying the magnitude of line patterns for outside region of a segmented nodule of the medical image [0068].

As per claim 8, Doi teaches:

identifying radial gradient index computed by the mean absolute value of a radial gradient projected along a radial direction for the inside of a segmented nodule of the medical image [0068];

identifying radial gradient index computed by the mean absolute value of a radial gradient projected along a radial direction for the outside of a segmented nodule of the medical image [0068];

identifying tangential gradient index computed by the mean absolute value of a radial gradient projected along a radial direction for the inside of a segmented nodule of the medical image [0068];

identifying tangential gradient index computed by the mean absolute value of a radial gradient projected along a radial direction for the outside of a segmented nodule of the medical image [0068].

As per claim 9, Doi teaches:

the step of obtaining the patient features consist of obtaining the sex of the patient [0064]; and

the step of extracting image features consists of extracting image features consists of extracting effective diameter of the pulmonary nodule [0067], contrast of the pulmonary nodule [0046], overlap measure of two gray-level histograms for the inside and outside regions of a segmented nodule of the medical image [0069], overlap measure of two gray-level histograms of the inside and outside region of a segmented nodule of an edge gradient of the medical image ([0064] and [0069], radial gradient index for an inside region of a segmented nodule of the medical image [0068], and peak value of a histogram for an inside regions of a segmented nodule of an edge gradient of the medical image ([0069] and [0088]).

As per claim 10, Doi teaches:

wherein the step of extracting image features consists of extracting the effective diameter of the pulmonary nodule [0087] and the contrast of the pulmonary nodule [0078].

As per claim 11, Doi teaches:

obtaining three medical images (Fig. 10, S60); and  
the step of evaluating if the pulmonary nodules are malignant is based on the examination of the three medical images (fig. 10, S80).

As per claims 12 and 13, they depend upon any of the rejected claims above and analogous remarks apply.

As per claim 14, Doi teaches:

a means for obtaining a medical image of the pulmonary nodule (fig. 10, S10);  
a means for obtaining patient features of a patient having the pulmonary nodule [0089];

a means for obtaining image features of the pulmonary nodule from the analysis of the medical image (fig. 10, S60).

***Remarks***

6. Claims 1-4, 6, 7 and 10-14 could have also been rejected under 35 U.S.C. 103(a) over the combination of Doi et al., US 5,289,374 and Ema et al., US 5,779,634. As Doi teaches most of the limitations regarding feature extraction and classifying nodules and Ema teaches collecting patient features (col. 1, ll. 25-30, Tables 5-10).

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mehrdad Dastouri whose telephone number is (703)



305-2438. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**MEHRDAD DASTOURI**  
**PRIMARY EXAMINER**



Mehrdad Dastouri  
Primary Examiner  
Art Unit 2623  
April 17, 2004